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Attorneys for Plaintiff,
IRIDEX CORPORATION

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

IRIDEX CORPORATION, a Delaware Corporation,

Plaintiff,

v.

QUANTEL MEDICAL, S.A., a French Corporation, QUANTEL USA, INC., a Montana Corporation, and QUANTEL, S.A., a French Corporation,

Defendants.

CASE NO.: 3:18-cv-153

COMPLAINT FOR PATENT INFRINGEMENT, BREACH OF CONTRACT AND TRADEMARK INFRINGEMENT

DEMAND FOR JURY TRIAL

Plaintiff Iridex Corporation, ("Iridex") files this Complaint against Quantel Medical, S.A. ("Quantel Medical"), Quantel, USA. Inc. ("Quantel USA"), and Quantel, S.A. (collectively "Quantel" or "Defendants") and demands a trial by jury. Iridex alleges as follows:

PARTIES

1. Plaintiff Iridex is a corporation organized under the laws of the State of Delaware, having its principal place of business at 1212 Terra Bella Avenue, Mountain View, California, 94043.

2. On information and belief, Quantel, S.A. is a corporation organized under the laws of France, with its principal place of business at 2 bis, Avenue du Pacifique, Z.A. de Courtaboeuf – BP 23, 91941 Les Ulis Cedex, France.

3. On information and belief, Quantel Medical is a corporation organized under the laws of France, with its principal place of business at 11 rue du Bois Joli – CS40015, 63808 Cournon d'Auvergne Cedex, France. On information and belief, Quantel Medical is some form of subsidiary of or otherwise controlled by Quantel, S.A.

4. On information and belief, Quantel USA is a corporation organized under the laws of the State of Montana, having its principal place of business at 49 Willow Peak Drive, Bozeman, Montana, 59718. On information and belief, Quantel USA is some form of subsidiary of or otherwise controlled by Quantel Medical.

BACKGROUND

5. Iridex developed and owns the MICROPULSE® laser technology for the non-invasive treatment of certain diseases of the eye. Iridex has obtained patents on MICROPULSE® laser technology, including U.S. Patent No. 7,771,417 (the "'417 patent"). Unlike conventional laser therapy, Iridex's MICROPULSE® laser technology uses microsecond pulse trains of laser emissions. This approach enhances control of the laser's clinical effects on target eye tissues, resulting in reduced injury to eye tissues while still producing comparable efficacy effects as compared to conventional laser therapy methods that visibly damage eye tissue.

6. In November of 2012, Iridex and Quantel Medical entered into a non–exclusive agreement (the "Agreement," attached hereto as Exhibit A) under which Iridex granted to Quantel

Medical and its affiliates access to Iridex's patented MICROPULSE® laser technology, including a license to the '417 patent.

7. During the term of the Agreement, Quantel has sold product under the license provided by the Agreement, in particular, its "Supra Scan 577nm Multispot and SubLiminal™ Laser" ("SS577"). According to Quantel's literature, the SS577 is a "true yellow 577 nm wavelength . . . multispot pattern scanning laser" with a "subthreshold treatment option" used to treat retinal disorders. (*See* http://www.quantel-medical.com/products/5-supra-scan-577 (last visited January 8, 2018).)

8. Quantel agreed that any action relating to the Agreement may be brought in Federal or State Courts in this District, and by the Agreement the parties irrevocably consent to jurisdiction in such courts for any proceeding relating to the Agreement.

9. On January 26, 2017, Iridex provided notice to Quantel of termination of the Agreement for material breach. Iridex demanded that Quantel cease selling products using the patented MICROPULSE® laser technology. Quantel agreed to do so. Upon information and belief, even after the termination, Quantel USA continued to sell the SS577. Quantel representatives at the American Academy of Ophthalmology annual meeting ("AAO"), which took place in New Orleans November 11 through 14, 2017 stated that the SS577 remains available in the U.S.

10. Earlier this year, Quantel received approval for its "EasyRet 577nm" product ("EasyRet"). On information and belief, Quantel representatives at AAO indicated that the core functionality of the EasyRet is the same as that of the SS577, but with a slightly different laser module. For all purposes relevant to this dispute, the EasyRet is the same as the SS577 and is used to treat the same retinal disorders as the SS577.

11. Upon information and belief, Quantel has conducted and continues to conduct business within the State of California and the Northern District of California, which business includes selling, offering to sell, and/or importing infringing products within the State of California and within the Northern District of California (see https://www.quantel-medical.com/contact/find_us (last visited January 8, 2018)).

12. Quantel's continued unauthorized use of Iridex's patented MICROPULSE® laser technology left Iridex no choice but to file the instant suit.

JURISDICTION AND VENUE

13. This is an action under federal patent law, federal trademark law, and an action for breach of contract. This Court has jurisdiction over the subject matter of the patent claim detailed herein pursuant to 28 U.S.C. section 1331 as a matter arising under the laws of the United States, and pursuant to section 1338, bestowing original jurisdiction to federal courts for patent claims. This Court has jurisdiction over the subject matter of the trademark claims detailed herein pursuant to 28 U.S.C. section 1331 as a matter arising under the laws of the United States and pursuant to 15 U.S.C. section 1121 and 28 U.S.C. section 1338, bestowing original jurisdiction to federal courts for trademark claims. This Court has jurisdiction over the subject matter of the contract claims under 28 U.S.C. section 1332 because, as noted in paragraphs 1-4 above, the parties have diverse citizenship and because Iridex is entitled to damages in excess of $75,000 on its breach of contract claims. This Court also has supplemental jurisdiction over the contract claims pursuant to 28.U.S.C. §1367 as it is closely related to and forms part of the same case or controversy as the patent claim.

14. Defendants are subject to this Court's personal jurisdiction and venue because, as discussed above in paragraph 8, Quantel Medical agreed that actions relating to the Agreement may be brought in the Northern District of California and consented to the Northern District of California's jurisdiction for claims relating to the Agreement, on behalf of itself, Quantel USA, and Quantel, S.A.

15. Upon information and belief, the SS577 and EasyRet (hereinafter collectively the "Infringing Products") are offered for sale through authorized sales representatives or entities located within this judicial district as well as through the website https://www.quantel-medical.com, which also contains instructions and encouragement for the practice of infringing acts.

16. Venue is proper in this Court under 28 U.S.C. § 1391(b), (c), (d) and 28 U.S.C. § 1400(b). Quantel also agreed to venue in the Northern District of California in the Agreement,

and has waived the right to challenge venue in this district for all claims related to the Agreement.

COUNT I—PATENT INFRINGEMENT

17. Iridex realleges and incorporates by reference each and every allegation contained in paragraphs 1-16 above as if fully set forth herein.

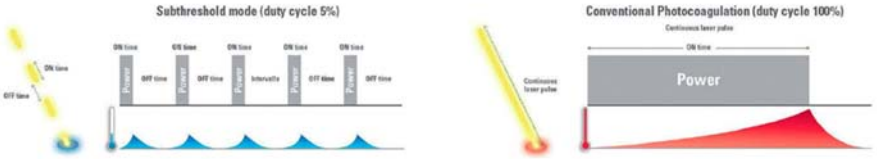
18. Iridex is the owner by assignment of the '417 Patent, entitled "Laser System with Short Pulse Characteristics and its Methods of Use" and naming William Telfair, Ronald Avisa, Stuart Mohr and David M. Buzawa as inventors. The '417 Patent duly and legally issued on August 10, 2010 from an application filed February 24, 2005. A copy of the '417 Patent is attached hereto as Exhibit B.

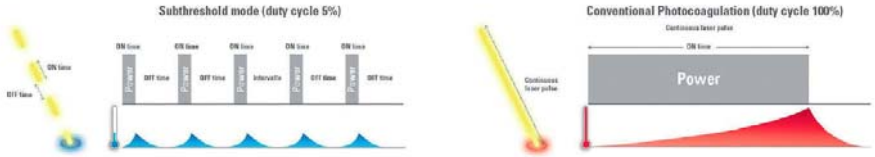
19. The '417 Patent is directed to a laser system and related methods for noninvasive treatment of diseases of the eye. Claim 1 of the '417 patent is exemplary. Upon information and belief, the Infringing Products and similar Quantel products meet all of the limitations of this exemplary claim, either literally or under the doctrine of equivalents, as reflected in the following charts:

Supra Scan 577

'417 Patent	**SS577**
1. A laser system, comprising:	The SS577 includes a laser and all the constituent parts necessary to the deployment and use of the laser. In short, it is a "laser system."  SUPRA 577.Y SPECIFICATIONS Laser: 577 nm, Solid State Technology (OPSL) Power at tissue up to: 2000 mW Pulse duration: 10 ms to continuous Monospot modes: Single, Repeat, Painting, Continuous Subthreshold mode: Train of microsecond pulses Adjustable duty cycle: from 5% to 25% Aiming beam: 635 – 650 nm Size: 14.6 (H) x 33 (W) x 30.7 (D) cm 4.8" (H) x 10.8" (W) x 10" (D) Weight: 10.5 kg – 23 lbs Cooling: By Peltier effect Power requirements: 100 to 240 VAC, 350 VA, 50/60 Hz (Exhibit C, SS577 Brochure at 6.)
a diode pump source; and	The product brochure describes the laser as an OPSL. Upon information and belief, OPSL stands for "Optically Pumped Semiconductor Laser." *See* http://www.laserfocusworld.com/articles/print/volume-42/issue-12/features/semiconductor-lasers-optically-pumped-semiconductor-lasers-expand-the-scope-of-potential-applications.html. Upon information and belief, the OPSL in the SS577 is sourced with a diode pump.

a frequency doubled solid state visible laser pumped by the diode pump source, the frequency doubled solid state visible laser producing an output of a train of pulses;	**SUPRA 577.Y SPECIFICATIONS** Laser: 577 nm, Solid State Technology (OPSL) Power at tissue up to: 2000 mW Pulse duration: 10 ms to continuous Monospot modes: Single, Repeat, Painting, Continuous Subthreshold mode: Train of microsecond pulses Adjustable duty cycle: from 5% to 25% Aiming beam: 635 – 650 nm Size: 14.6 (H) x 33 (W) x 30.7 (D) cm 4.8" (H) x 10.8" (W) x 10" (D) Weight: 10.5 kg – 23 lbs Cooling: By Peltier effect Power requirements: 100 to 240 VAC, 350 VA, 50/60 Hz (Exhibit C, SS577 Brochure at 6; see id. at 2-3.) The product brochure indicates that the laser is solid state and that its output wavelength is 577 nm. Light at wavelengths of 577nm is within the visible spectrum. (See https://en.wikipedia.org/wiki/Visible_spectrum (last visited January 8, 2018).) Upon information and belief, 577nm OPSL lasers have a fundamental near-IR output wavelength that is frequency doubled to output 577nm. Further, the brochure states that the laser output in "Subthreshold mode" consists of a train of pulses.
a photodetector generating a signal; and	The SS577 complies with 21 CFR 1040.10 and International Standard IEC 60825-1 for the safety of laser products.  (Exhibit C, SS577 Brochure at 6.) 21 CFR 1040.11 provides that each class IV medical laser product incorporate "a means for the measurement of the level of that laser radiation intended for irradiation of the human body." International Standard IEC 60825-1 for the safety of laser products, requires: **6.7 Laser radiation emission warning** **6.7.1** Each Class 3R laser system in the wavelength range below 400 nm and above 700 nm and each Class 1C, Class 3B and Class 4 laser system shall satisfy the following. **6.7.2** A warning device shall give an audible or visible signal when the laser system is switched on or if any capacitor banks of a pulsed laser are being charged or have not positively discharged. The warning device shall be fail-safe or redundant. Any visible warning device shall be clearly visible through protective eyewear specifically designed for the wavelength(s) of the emitted laser radiation. The visible warning device(s) shall be located so that viewing does not require exposure to laser radiation in excess of the AEL for Class 1M and 2M.

	This standard requires detection of the laser system operation and generation of a signal when in operation. Upon information and belief, the SS577 is sold in England and must comply with BSI (British Standards Institution) requirements for medical laser products, BS EN 60601-2-22:2013. BS EN 60601-2-22:2013 section 201.10.4(d)-(e), includes requirements for laser ready indicators and laser emission indicators on lasers and light emitting diodes: Additionally, the laser equipment shall incorporate: d) Laser ready indicator Laser equipment shall incorporate a visible LASER READY INDICATOR, which shall be illuminated when emission of the WORKING BEAM is possible upon actuation of the control switch, to allow appropriate safety precautions to be taken. e) Laser emission indicators In addition to the LASER READY INDICATOR, laser equipment shall be equipped with a visible and an audible signal, which clearly indicate that emission of LASER RADIATION in excess of the AEL for CLASS 3R is taking place. The LASER EMISSION INDICATORS shall be designed as described in 4.7 of IEC 60825-1. Both, the LASER READY INDICATOR and the visible LASER EMISSION INDICATOR shall be visible through laser protective eyewear worn by those present in the laser area. Provided that one of the LASER EMISSION INDICATORS is clearly visible or audible to the persons in the vicinity of the operational control or laser APERTURE, the 2 m distance requirement of Subclause 4.7.3 of IEC 60825-1 is not applicable. NOTE 1 Since this standard requires a LASER READY INDICATOR and two LASER EMISSION INDICATORS, the FAIL SAFE or redundancy requirement in Subclause 4.7.2 of IEC 60825-1 is not applicable. NOTE 2 AIMING BEAMS are not considered to be indicator lights. Upon information and belief, any such means for measurement necessarily includes a photodetector for generating a signal.
a controller including a software control loop that, in response to the signal from the photodetector, alters drive current to the diode pump source within about a millisecond, and a hardware control loop that, in response to the signal from the photodetector, controls timing of the train of pulses to within a microsecond so that the controller provides instructions for the output of the train of pulses	● Subthreshold Mode: In addition to monospot and multispot delivery modes, Supra Scan 577 features the Subthreshold mode. The use of this subthreshold treatment mode converts each laser shot into a "pulse envelope" composed of a customizable train of short pulses, allowing the operator to fully adjust the pulse duration (On Time) and interval (Off Time). This fined-tuned control of the laser treatment settings ensures a precise management of the thermal effect on the targeted tissues.  (Exhibit C, SS577 Brochure at 3.) ● Subthreshold Mode: Composed of a train of extremely short microsecond pulses, this subthreshold treatment mode (non-visible laser impacts) is a tissue sparing treatment mode avoiding scarring [7,8] while treating Diabetic Macular Edema [7] and Central Serous Chorioretinopathy [8]. (Exhibit C, SS577 Brochure at 2.) Upon information and belief, the SS577 uses both hardware and software to provide instructions for the output of the trains of pulses.

	Upon information and belief, the SS577 complies with International Standard IEC 60825-1 for the safety of laser products, which requires: **6.16 Power limiting circuit** If a power-control circuit is employed to limit the electrical power to the laser emitting device such that the AEL of the specified laser class is not exceeded under operation, it shall limit emission under reasonably foreseeable single fault conditions as well, including considering the temperature dependence of the device. NOTE This typically applies to semiconductor diode lasers where a current spike may cause radiation above the AEL. The recommended operating parameters for diode lasers (e.g. current and temperature) are usually well below the gain saturation regime to ensure good spectral characteristics. Therefore a considerable increase of laser emission can occur beyond the recommended parameters. Because the SS577 has variable power capability as determined through a control circuit, in order to satisfy IEC 60825-1, it must be able to control the power in response to detecting the current power emitted.
with on times of 25 microseconds to 10 milliseconds per pulse such that the train of pulses is sufficient for photoactivation of a therapeutic healing response in tissue at a target site, and off times of 75 to 100,000 microseconds such that the train of pulses is insufficient to induce traditional photocoagulation of the tissue at the target site,	● **Multispot Mode:** Characterized by the use of short pulse durations (10-20ms) and by the emission of customizable patterns, the multispot treatment mode offers many advantages over classical single spot treatments: ● **Subthreshold Mode:** Composed of a train of extremely short microsecond pulses, this subthreshold treatment mode (non-visible laser impacts) is a tissue sparing treatment mode avoiding scarring [7,8] while treating Diabetic Macular Edema [7] and Central Serous Chorioretinopathy [8]. (Exhibit C SS577 Brochure at 2.) ● **Subthreshold Mode:** In addition to monospot and multispot delivery modes, Supra Scan 577 features the Subthreshold mode. The use of this subthreshold treatment mode converts each laser shot into a "pulse envelope" composed of a customizable train of short pulses, allowing the operator to fully adjust the pulse duration (On Time) and interval (Off Time). This fined-tuned control of the laser treatment settings ensures a precise management of the thermal effect on the targeted tissues.  (Exhibit C SS577 Brochure at p. 3.) differentiate itself from conventional photocoagulation as it minimizes the collateral damage and results in no visible burns. **How MicroPulse technology works** The MicroPulse laser mode delivers energy in succeeding train of very short pulses, with alternative "on" and "off" times that have led to the duty cycle concept. The duty cycle is defined as the length of time of "power on" divided by the total time the laser is used. For example, a 5% duty cycle means that each MicroPulse of energy is "on" for 100 µs followed by 1900 µs in the "off" mode. There is a reason the laser is off much longer than it is on—we need to ensure there is enough time for the surrounding tissues to cool to eliminate the possibility of thermal damage to the inner retina. This cycle is repeated multiple times within one laser shot, ie, 100 times with a 5% duty cycle (Figure 2).

	(*See* http://www.quantel-medical.com/upload/products/product-5/download_file_en_577nmMicroPulseTreatmentGuidelines_Fauser_Chong_RetinaToday_12_2015.pdf (last visited January 8, 2018) (discussing using a SS577 Laser with a 5% duty cycle where the laser is on for 100µs and off for 1900µs); *see also* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4179114/ (last visited January 8, 2018) (discussing using a SS577 Laser where for each pulse the laser is on for 180 µs and off for 1ms).)
the photodetector coupling the controller to the pulsed output so that a power of the pulsed output is within less than 10% of a desired power.	 (Exhibit C SS577 Brochure at p. 6.) 21 CFR 1040.11 provides that each class IV medical laser product incorporate "a means for the measurement of the level of that laser radiation intended for irradiation of the human body" and that "[s]uch means may have an error in measurement of no more than 20 percent when calibrated in accordance with paragraph (a)(2) of this section." Upon information and belief, systems such as the SS577 designed to meet 21 CFR 1040.11 and similar regulations target substantially narrower ranges of 10 percent or less in order to ensure compliance. BSI (British Standards Institution) requirements for medical laser products, BS EN 60601-2-22:2013 section 201.10.4(d)-(e), includes requirements for laser ready indicators and laser emission indicators on lasers and light emitting diodes: Additionally, the laser equipment shall incorporate: d) Laser ready indicator Laser equipment shall incorporate a visible LASER READY INDICATOR, which shall be illuminated when emission of the WORKING BEAM is possible upon actuation of the control switch, to allow appropriate safety precautions to be taken. e) Laser emission indicators In addition to the LASER READY INDICATOR, laser equipment shall be equipped with a visible and an audible signal, which clearly indicate that emission of LASER RADIATION in excess of the AEL for CLASS 3R is taking place. The LASER EMISSION INDICATORS shall be designed as described in 4.7 of IEC 60825-1. Both, the LASER READY INDICATOR and the visible LASER EMISSION INDICATOR shall be visible through laser protective eyewear worn by those present in the laser area. Provided that one of the LASER EMISSION INDICATORS is clearly visible or audible to the persons in the vicinity of the operational control or laser APERTURE, the 2 m distance requirement of Subclause 4.7.3 of IEC 60825-1 is not applicable. NOTE 1 Since this standard requires a LASER READY INDICATOR and two LASER EMISSION INDICATORS, the FAIL SAFE or redundancy requirement in Subclause 4.7.2 of IEC 60825-1 is not applicable. NOTE 2 AIMING BEAMS are not considered to be indicator lights.

BS EN 60601-2-22:2013 section 201.12.1.101 and 201.12.4.2 further requires power to be controlled within specified limits:

201.12.1.101 Indication of LASER OUTPUT

Laser equipment shall incorporate a means for the indication of the preset level of the output of the WORKING BEAM.

The indication shall be in SI units.

The actual LASER OUTPUT measured in the WORKING AREA shall not deviate from the set value by more than ±20 %. Where the laser equipment is calibrated in watts and incorporates a timer-controlled exposure system, the LASER ENERGY shall not deviate by more than ±20 %.

This subclause does not apply if the LASER OUTPUT is fixed by the manufacturer and is not adjustable. In this case, the fixed LASER OUTPUT shall be stated by labelling.

Compliance is checked by inspection and measurements.

201.12.4.2 Indication of parameters relevant to safety

Addition:

The indicated LASER OUTPUT emitted by the laser equipment shall not deviate from the preset value by more than ±20 %. A measured quantity, electrical or optical, which is directly related to the LASER OUTPUT generated, shall be monitored during operation. The monitoring shall be carried out at intervals shorter than the failure tolerance time (see Annex AA, rationale to 201.12.4.4).

Typical solutions are:

- closed-loop system;
- open-loop system with a visible and/or audible out-of-tolerance warning.

Compliance test: during use under NORMAL CONDITIONS, as well as under any reasonably foreseeable SINGLE FAULT CONDITION, the LASER OUTPUT is checked to be within the allowed tolerance or the required warning is given otherwise.

The calibration of the system is to be checked at regular intervals against the LASER POWER (or LASER ENERGY) actually emitted on the WORKING AREA. An appropriate method shall be described in the instructions for use in accordance with 201.7.9.2.101, 4th dash.

Upon information and belief, the SS577 is sold in England and must comply with this standard.

EasyRet

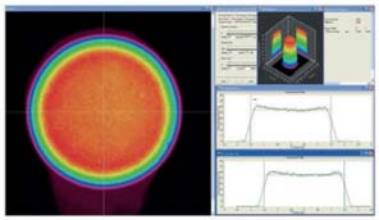
'417 Patent	EasyRet
1. A laser system, comprising:	 (Exhibit D, EasyRet Brochure at 6.)
a diode pump source; and	"In fiber lasers, the lasing medium is composed of an optical fiber doped with rare earth elements and optically pumped by diodes." (Exhibit D, EasyRet Brochure at 5.)
a frequency doubled solid state visible laser pumped by the diode pump source, the frequency doubled solid state visible laser producing an output of a train of pulses;	 (Exhibit D, EasyRet Brochure at 6.)

Fiber Laser Technology:

Stemming from the ELBA™ technology, developed and successfully marketed by Quantel Laser for various applications, this new generation of laser cavity provides unique advantages:

- An excellent beam quality ensuring a homogeneous laser spot profile (top hat)
- The emission of pure 577nm yellow wavelength
- An extended lifetime thanks to a simple, compact and reliable technology

The fiber laser technology is a variation of the standard solid-state laser technology.
In fiber lasers, the lasing medium is composed of an optical fiber doped with rare earth elements and optically pumped by diodes.



(Exhibit D, EasyRet Brochure at 5.)

(*See also* https://www.quantel-laser.com/en/products/item/elba-.html (last visited January 8, 2018) (discussing Quantel's ELBA-C fiber laser for use in ophthalmology capable of outputting "any wavelength in the 530-577 nm range (green – yellow)" using an infrared laser with an adjustable range spanning 1060 nm to 1160 nm, which is then "delivered . . . to a wavelength conversion module" to produce the ultimate output wavelength).)

Light at wavelengths of 577nm is within the visible spectrum. (See https://en.wikipedia.org/wiki/Visible_spectrum (last visited January 8, 2018).)

"The fiber laser technology is a variation of the standard solid-state laser technology." (Ex. D, EasyRet Brochure at 5.) A fiber laser is a type of solid-state laser. See https://www.rp-photonics.com/solid_state_lasers.html.

MultiSpot Mode:

Characterized by the use of short pulse durations from 10 to 20 ms, the MultiSpot treatment mode offers many advantages over classical treatments:

- Less heat diffusion to the retina and choroid, less damage to the retinal nerve fiber layer [3,4]
- Comfortable treatment better tolerated by patients [5]
- Treatment time reduction (full PRP in 1 session) [6]

The MultiSpot treatment mode can be delivered through 5 customizable patterns for better adaptation to the treatment site.
Single spot - Squares - Circles - Triple arcs - Macular grid

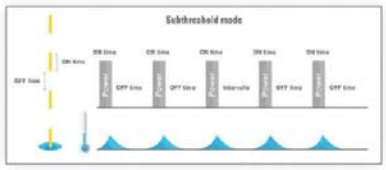
MicroPulse® Mode:

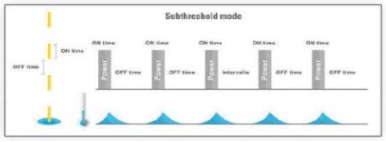
Composed of a train of extremely short microsecond pulses, this subthreshold treatment mode (non-visible laser impacts) is a tissue sparing treatment mode avoiding scarring [7,8] while treating Diabetic Macular Edema [7] and Central Serous Chorioretinopathy [8].

The MicroPulse® treatment mode can be delivered through 3 customizable patterns for better adaptation to the treatment site.

(Exhibit D, EasyRet Brochure at 5.)

a photodetector generating a signal; and	The EasyRet complies with 21 CFR 1040.10 and International Standard IEC 60825-1 for the safety of laser products  (Exhibit D, EasyRet Brochure at 6.) 21 CFR 1040.11 provides that each class IV medical laser product incorporate "a means for the measurement of the level of that laser radiation intended for irradiation of the human body." Quantel's information regarding its ELBA-C laser, which outputs 577nm for ophthalmological applications and, upon information and belief is the laser module in the EasyRet, states that this laser has output power stability of less than one percent. (*See* https://www.quantel-laser.com/tl_files/client/MY%20QUANTEL%20SPACE/Sales%20Literature/ELBA-PLATFORM_Specs_EN_092016.pdf (last visited January 8, 2018).) The International Standard IEC 60825-1 for the safety of laser products, requires: **6.7 Laser radiation emission warning** **6.7.1** Each Class 3R laser system in the wavelength range below 400 nm and above 700 nm and each Class 1C, Class 3B and Class 4 laser system shall satisfy the following. **6.7.2** A warning device shall give an audible or visible signal when the laser system is switched on or if any capacitor banks of a pulsed laser are being charged or have not positively discharged. The warning device shall be fail-safe or redundant. Any visible warning device shall be clearly visible through protective eyewear specifically designed for the wavelength(s) of the emitted laser radiation. The visible warning device(s) shall be located so that viewing does not require exposure to laser radiation in excess of the AEL for Class 1M and 2M. This standard requires detection of the laser system operation and generation of a signal when in operation. Upon information and belief, the EasyRet is sold in England and must comply with BSI (British Standards Institution) requirements for medical laser products, BS EN 60601-2-22:2013. BS EN 60601-2-22:2013 section 201.10.4(d)-(e), includes requirements for laser ready indicators and laser emission indicators on lasers and light emitting diodes:

	Additionally, the laser equipment shall incorporate: d) Laser ready indicator Laser equipment shall incorporate a visible LASER READY INDICATOR, which shall be illuminated when emission of the WORKING BEAM is possible upon actuation of the control switch, to allow appropriate safety precautions to be taken. e) Laser emission indicators In addition to the LASER READY INDICATOR, laser equipment shall be equipped with a visible and an audible signal, which clearly indicate that emission of LASER RADIATION in excess of the AEL for CLASS 3R is taking place. The LASER EMISSION INDICATORS shall be designed as described in 4.7 of IEC 60825-1. Both, the LASER READY INDICATOR and the visible LASER EMISSION INDICATOR shall be visible through laser protective eyewear worn by those present in the laser area. Provided that one of the LASER EMISSION INDICATORS is clearly visible or audible to the persons in the vicinity of the operational control or laser APERTURE, the 2 m distance requirement of Subclause 4.7.3 of IEC 60825-1 is not applicable. NOTE 1 Since this standard requires a LASER READY INDICATOR and two LASER EMISSION INDICATORS, the FAIL SAFE or redundancy requirement in Subclause 4.7.2 of IEC 60825-1 is not applicable. NOTE 2 AIMING BEAMS are not considered to be indicator lights. Upon information and belief, any such means for measurement necessarily includes a photodetector for generating a signal.
a controller including a software control loop that, in response to the signal from the photodetector, alters drive current to the diode pump source within about a millisecond, and a hardware control loop that, in response to the signal from the photodetector, controls timing of the train of pulses to within a microsecond so that the controller provides instructions for the output of the train of pulses	● Subthreshold Technology: In addition to SingleSpot and MultiSpot delivery modes, Easyret® features the Subthreshold technology. The use of this subthreshold treatment mode converts each laser shot into a "pulse envelope" composed of a customizable train of short pulses, allowing the operator to fully adjust the pulse duration (On Time) and interval (Off Time). This fined-tuned control of the laser treatment settings ensures a precise management of the thermal effect on the targeted tissues.  (Exhibit D, EasyRet Brochure at 5.) ● Subthreshold Mode: Composed of a train of extremely short microsecond pulses, this subthreshold treatment mode (non-visible laser impacts) is a tissue sparing treatment mode avoiding scarring [7,8] while treating Diabetic Macular Edema [7] and Central Serous Chorioretinopathy [8]. (Exhibit D, EasyRet Brochure at 2.) Upon information and belief, the EasyRet uses both hardware and software to provide instructions for the output of the trains of pulses. Upon information and belief, the EasyRet complies with International Standard IEC 60825-1 for the safety of laser products, which requires: **6.16 Power limiting circuit** If a power-control circuit is employed to limit the electrical power to the laser emitting device such that the AEL of the specified laser class is not exceeded under operation, it shall limit emission under reasonably foreseeable single fault conditions as well, including considering the temperature dependence of the device. NOTE This typically applies to semiconductor diode lasers where a current spike may cause radiation above the AEL. The recommended operating parameters for diode lasers (e.g. current and temperature) are usually well below the gain saturation regime to ensure good spectral characteristics. Therefore a considerable increase of laser emission can occur beyond the recommended parameters.

	Because the EasyRet has variable power capability as determined through a control circuit, in order to satisfy IEC 60825-1, it must be able to control the power in response to detecting the current power emitted.
with on times of 25 microseconds to 10 milliseconds per pulse such that the train of pulses is sufficient for photoactivation of a therapeutic healing response in tissue at a target site, and off times of 75 to 100,000 microseconds such that the train of pulses is insufficient to induce traditional photocoagulation of the tissue at the target site,	**MultiSpot Mode:** Characterized by the use of short pulse durations from 10 to 20 ms, the MultiSpot treatment mode offers many advantages over classical treatments: **Subthreshold Mode:** Composed of a train of extremely short microsecond pulses, this subthreshold treatment mode (non-visible laser impacts) is a tissue sparing treatment mode avoiding scarring [7,8] while treating Diabetic Macular Edema [7] and Central Serous Chorioretinopathy [8]. (Exhibit D, EasyRet Brochure at 2.) **Subthreshold Technology:** In addition to SingleSpot and MultiSpot delivery modes, Easyret® features the Subthreshold technology. The use of this subthreshold treatment mode converts each laser shot into a "pulse envelope" composed of a customizable train of short pulses, allowing the operator to fully adjust the pulse duration (On Time) and interval (Off Time). This fined-tuned control of the laser treatment settings ensures a precise management of the thermal effect on the targeted tissues.  (Ex. D, EasyRet Brochure at 5.) results in no visible burns. Basically, the laser beam is cut into small pieces of on time and long pieces of off time. This allows the tissue to cool, which results in no scarring. This led to the duty cycle concept, which is the length of time the laser is on divided by the total time the laser is used. The use of the recommended settings results in no fibrous damage because the laser is on for 100 µs and off for 1,900 µs (5% duty cycle) (Figure 1). (*See* https://www.quantel-medical.com/products/download/183/en/download_file_en_EASYRET_AN_14_-_Micropulse_for_CRSC.Fauser.Retina_Today.02.2017 (last visited January 8, 2018).)

the photodetector coupling the controller to the pulsed output so that a power of the pulsed output is within less than 10% of a desired power.	The EasyRet complies with 21 CFR 1040.10 and International Standard IEC 60825-1 for the safety of laser products  (Exhibit D EasyRet Brochure at p. 6.) 21 CFR 1040.11 provides that each class IV medical laser product incorporate "a means for the measurement of the level of that laser radiation intended for irradiation of the human body" and that "[s]uch means may have an error in measurement of no more than 20 percent when calibrated in accordance with paragraph (a)(2) of this section." BSI (British Standards Institution) requirements for medical laser products, BS EN 60601-2-22:2013 section 201.10.4(d)-(e), includes requirements for laser ready indicators and laser emission indicators on lasers and light emitting diodes: Additionally, the laser equipment shall incorporate: d) Laser ready indicator Laser equipment shall incorporate a visible LASER READY INDICATOR, which shall be illuminated when emission of the WORKING BEAM is possible upon actuation of the control switch, to allow appropriate safety precautions to be taken. e) Laser emission indicators In addition to the LASER READY INDICATOR, laser equipment shall be equipped with a visible and an audible signal, which clearly indicate that emission of LASER RADIATION in excess of the AEL for CLASS 3R is taking place. The LASER EMISSION INDICATORS shall be designed as described in 4.7 of IEC 60825-1. Both, the LASER READY INDICATOR and the visible LASER EMISSION INDICATOR shall be visible through laser protective eyewear worn by those present in the laser area. Provided that one of the LASER EMISSION INDICATORS is clearly visible or audible to the persons in the vicinity of the operational control or laser APERTURE, the 2 m distance requirement of Subclause 4.7.3 of IEC 60825-1 is not applicable. NOTE 1 Since this standard requires a LASER READY INDICATOR and two LASER EMISSION INDICATORS, the FAIL SAFE or redundancy requirement in Subclause 4.7.2 of IEC 60825-1 is not applicable. NOTE 2 AIMING BEAMS are not considered to be indicator lights. BS EN 60601-2-22:2013 section 201.12.1.101 and 201.12.4.2 further requires power to be controlled within specified limits:

	201.12.1.101 Indication of LASER OUTPUT Laser equipment shall incorporate a means for the indication of the preset level of the output of the WORKING BEAM. The indication shall be in SI units. The actual LASER OUTPUT measured in the WORKING AREA shall not deviate from the set value by more than ±20 %. Where the laser equipment is calibrated in watts and incorporates a timer-controlled exposure system, the LASER ENERGY shall not deviate by more than ±20 %. This subclause does not apply if the LASER OUTPUT is fixed by the manufacturer and is not adjustable. In this case, the fixed LASER OUTPUT shall be stated by labelling. *Compliance is checked by inspection and measurements.* **201.12.4.2 Indication of parameters relevant to safety** *Addition:* The indicated LASER OUTPUT emitted by the laser equipment shall not deviate from the preset value by more than ±20 %. A measured quantity, electrical or optical, which is directly related to the LASER OUTPUT generated, shall be monitored during operation. The monitoring shall be carried out at intervals shorter than the failure tolerance time (see Annex AA, rationale to 201.12.4.4). Typical solutions are: – closed-loop system; – open-loop system with a visible and/or audible out-of-tolerance warning. *Compliance test: during use under NORMAL CONDITIONS, as well as under any reasonably foreseeable SINGLE FAULT CONDITION, the LASER OUTPUT is checked to be within the allowed tolerance or the required warning is given otherwise.* The calibration of the system is to be checked at regular intervals against the LASER POWER (or LASER ENERGY) actually emitted on the WORKING AREA. An appropriate method shall be described in the instructions for use in accordance with 201.7.9.2.101, 4th dash. Upon information and belief, the EasyRet is sold in England and must comply with this standard.

20. On information and belief, Quantel has sold and/or offered the Infringing products for sale to end-users and re-sellers, and has imported or caused the importation of the SS577, EasyRet and similar Quantel products into the United States in a manner that results in infringement of at least claims 1-3, 6-9, 11, 13-22, 24, 25, and 28-31 of the ’417 patent. On information and belief, Quantel knew or should have known that its resellers would directly infringe the claims of the ’417 by selling the SS577, EasyRet and similar Quantel products, and Quantel knew or should have known that its end users would use the SS577, EasyRet and similar Quantel products in direct infringement of the ’417 patent. On information and belief, Quantel induced infringement of the ’417 patent by selling the SS577, EasyRet and similar Quantel products with the specific intent of encouraging end-users to infringe claims of the ’417 without a reasonable, good faith belief that its actions did not induce infringement. Quantel’s inducement of

infringement arises, at least in part, because Quantel encourages end-users to use the SS577, EasyRet and similar Quantel products to perform methods claimed in the '417 patent.

21. Quantel's infringement has injured Iridex and Iridex is entitled to recover damages adequate to compensate for such infringement, including lost profits, but in no case less than a reasonable royalty for Quantel's use of the invention claimed by the '417 patent.

22. Since the termination of the Agreement, Quantel's direct and indirect infringement has and continues to be willful and deliberate, entitling Iridex to enhanced damages and attorneys' fees per 35 U.S.C. §§ 284-285.

23. Quantel's infringement of the '417 patent has irreparably injured Iridex and will continue to injure Iridex unless and until the Court enters an injunction prohibiting Quantel and those acting in concert with or on behalf of Quantel from committing further acts of infringement by enjoining the further use, offer for sale, sale, and importation into the United States of the SS577, EasyRet and similar Quantel products.

COUNT II—BREACH OF CONTRACT

24. Iridex realleges and incorporates by reference each and every allegation contained in paragraphs 1-23 above as if fully set forth herein.

25. The Agreement was validly entered by Iridex and Quantel Medical.

26. Upon information and belief, Iridex performed all or substantially all of its obligations under the Agreement.

27. The Agreement prohibits Quantel from taking action that could reasonably be expected to harm or prejudice the reputation of the MICROPULSE® technology. Quantel provides its physician customers with instructions and/or training on the use of the product licensed under the Agreement, including the SS577 marked with the MICROPULSE® mark. With respect to the SS577, this includes the settings for various parameters for the operation of the SS577 laser. Whether through deficiencies in the instructions or training or as a result of defects in the Quantel product, patients' experience with the Quantel MICROPULSE® branded product did not always yield the benefits of the MICROPULSE® technology. In one instance reported to the United States Food and Drug Administration ("FDA"), a physician performed "micropulse

[sic] following the settings on [a SS577]" and, according to the report on the incident, caused damage to the eye that reduced the patient's visual acuity from 20/25 prior to the procedure to 20/200 – legally blind – following the procedure. See the Medical Device Adverse Report submitted to the FDA as report number 3031037-2015-00001 (attached hereto as Exhibit E). Upon information and belief, either Quantel failed to ensure that the instructions and training it provided its doctors would result in the safe delivery of the laser energy to the patient's eye or it put defective product into the marketplace. Regardless of the cause, Quantel took action that resulted in injury to patients, thereby harming the reputation and goodwill associated with MICROPULSE® laser technology products. Quantel thereby breached the Agreement and caused harm to the value of Iridex's MICROPULSE® mark and reputation in excess of $75,000.

COUNT III—TRADEMARK INFRINGEMENT

28. Iridex realleges and incorporates by reference each and every allegation contained in paragraphs 1-27 above as if fully set forth herein.

29. Iridex is the owner of the United States Trademark Registration No. 4550188 on the principal register for the "MICROPULSE®" mark for "lasers for surgical and medical use in the treatment of eye disease; medical laser delivery devices for use in the treatment of eye disease."

30. During the term of the Agreement, Quantel had a limited right to use the MICROPULSE® mark. That right was limited to labeling the outside of products covered by the Agreement with the "MICROPULSE®" mark. Upon information and belief, during the term of the agreement, Quantel used the MICROPULSE® mark in manners beyond mere labeling of the outside of products covered by the Agreement.

31. Upon information and belief, after the termination of the Agreement, Quantel continued to use the MICROPULSE® mark, despite no longer having any right to do so. For example, upon information and belief, after the termination of the agreement, Quantel knowingly and intentionally used the MICROPULSE® mark in the advertisement and solicitation of its products.

32. Quantel's use of Iridex's MICROPULSE® mark is likely to cause confusion,

deception, and mistake by creating the false and misleading impression that Quantel's goods are manufactured, distributed by, associated with, connected with, or have the sponsorship, endorsement, or approval of Iridex.

33. Quantel's continued use of Iridex's MICROPULSE® mark will continue to cause a likelihood of confusion and deception of members of the trade and public, and, additionally, injury to Iridex's goodwill and reputation, for which Iridex has no adequate remedy at law.

34. Quantel's actions demonstrate an intentional, willful, and malicious intent to trade on the goodwill associated with Iridex's MICROPULSE® mark to Iridex's great and irreparable harm.

35. Quantel has caused and is likely to continue causing substantial injury to the public and to Iridex, and Iridex is entitled to injunctive relief and to recover Quantel's profits, actual damages, enhanced profits and damages, costs, and reasonable attorneys' fees under 15 U.S.C. §§ 1114, 1116, and 1117.

PRAYER FOR RELIEF

WHEREFORE, Iridex prays for relief in its favor, as follows:

A. A judgment that Quantel infringed, directly and/or indirectly, literally and/or under the doctrine of equivalents, the '417 Patent in violation of 35 U.S.C. § 271;

B. An order and judgment preliminarily and permanently enjoining Quantel, officers, agents, subsidiaries and employees, and those in privity or in active concert with Quantel, from further activities that constitute infringement of the '417 Patent;

C. Damages sufficient to compensate Iridex for its lost profits resulting from Quantel's infringement of the '417 Patent, but no less than a reasonable royalty;

D. Treble damages for Quantel's willful infringement of the '417 Patent pursuant to 35 U.S.C. § 284 and attorneys' fees incurred in connection with the patent infringement claims pursuant to 35 U.S.C. § 285;

E. A judgment that Quantel engaged in actions that it should have reasonably anticipated would harm the reputation and goodwill associated with MICROPULSE® laser technology products in direct breach of the Agreement;

F. A judgment that Defendants have infringed Iridex's MICROPULSE® trademark;

G. Damages sufficient to compensate Iridex for the reputational and goodwill losses to the MICROPULSE® mark;

H. On Counts I and III, an award of Iridex's reasonable attorneys' fees and judgment and post-judgement interests, costs and the expenses of this action; and

I. Any other relief the Court deems appropriate.

DATED: January 8, 2018

Respectfully submitted,

KILPATRICK TOWNSEND & STOCKTON LLP

By: */s/ Scott E. Kolassa*

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REQUEST FOR TRIAL BY JURY

Iridex hereby requests that this case be tried to a jury.

DATED: January 8, 2018

Respectfully submitted,

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By: */s/ Scott E. Kolassa*

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